

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA  
BILLINGS DIVISION**

TOBY C. MCADAM,

Plaintiff,

vs.

UNITED STATES FOOD AND  
DRUG ADMINISTRATION;  
MARGARET HAMBUR,  
COMMISSIONER OF FDA;  
CHARLES BREEN, DIRECTOR  
OF SEATTLE DISTRICT OF  
FDA; MARIAM R. BURBACH,  
ACTING DIRECTOR OF  
SEATTLE DISTRICT OF FDA;  
LISA ALTHAR, COMPLIANCE  
OFFICE OF SEATTLE DISTRICT  
OF FDA; et. al,

Defendants.

CV-14-47-BLG-SPW-CSO

**ORDER**

**I. INTRODUCTION**

Plaintiff Toby C. McAdam (“McAdam”) brings the present action against the United States Food and Drug Administration (“FDA”) and several FDA employees and officers in their individual and official capacities. *See Cmplt (ECF 1)*<sup>1</sup>. He alleges violations of his

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<sup>1</sup>“ECF” refers to the document as numbered in the Court’s Electronic Case Files. *See The Bluebook, A Uniform System of Citation*,

constitutional rights of equal protection and free speech, a tort claim for slander, and several claims relating to this Court's November 4, 2010 Consent Decree of Permanent Injunction. *Id. at 4-10.*

Defendant FDA and individual Defendants Margaret Hambur, Charles Breen, Mariam R. Burback, and Lisa Althar, appearing in their official capacities only, have filed a Motion to Dismiss pursuant to Rules 12(b)(1), (5), and (6)<sup>2</sup>. *See ECF 6.* The individual Defendants represent that they will enter separate appearances in their individual capacities when they are properly served under Rule 4. *See Defts' Br. (ECF 8) at 6, FN 1.*

## **II. BACKGROUND**

In October 2010, the United States filed a Complaint for Permanent Injunction against McAdam, alleging that McAdam regularly sold unapproved drugs in interstate commerce that purported to treat a variety of serious diseases, in violation of the Federal Food, Drug, and Cosmetic Act. *See U.S. v. McAdam, CV 10-128-BLG-SEH ("McAdam I"), ECF 1.* Upon the parties' consent, the Court entered a

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§ 10.8.3.

<sup>2</sup>References to "Rules" are to the Federal Rules of Civil Procedure unless otherwise indicated.

Consent Decree of Permanent Injunction (“Consent Decree”) on November 4, 2010, enjoining McAdam from “introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packaging, labeling, holding, selling, or distributing” a wide array of products, unless certain specified prerequisites had been satisfied.

*McAdam I*, ECF 5 at 4-6. The Consent Decree identified a number of specifically-prohibited products produced by McAdam, including several varieties of “black salves,” including a black salve with “Lugol’s Iodine.” *McAdam I*, “Schedule A” (ECF 5-1).

On February 14, 2012, McAdam filed a motion to set aside the Consent Decree, alleging that he had been coerced and intimidated into signing the Consent Decree, and that he had been denied equal treatment under the Montana and United States Constitutions. *See McAdam I*, ECF 8. This Court denied McAdam’s motion, finding no coercion or intimidation in the execution of the Consent Decree, nor a violation of McAdam’s equal protection rights. *McAdam I*, ECF 12 at 5, 10-11.

On February 22, 2013, in response to further alleged violations of the Consent Decree, the United States filed a petition seeking an order

to show cause why McAdam should not be held in civil contempt.

*McAdam I*, ECF 18. After a show cause hearing held on October 21, 2013, this Court found “clear and convincing evidence that McAdam has failed to comply with several requirements of the Consent Decree.”

*McAdam I*, ECF 47 at 14. This Court recommended that the United States’ petition for judgment of civil contempt be granted, and that McAdam be directed to pay \$80,000 in liquidated damages and \$4,936.48 in fees and costs. *Id.* at 19. Judge Haddon adopted this Court’s recommendation in full, specifically ordering McAdam to (1) “immediately cease all manufacturing, processing, packaging, labeling, holding, selling, and/or distributing all products intended to be ingested by, or applied topically to, humans or animals, including, without limitation, any drugs and/or dietary supplements[,]” (2) immediately shut down his website and his business’s Facebook page, (3) removal all products from Amazon.com, and (4) remove any related telephone listings from phone books. *McAdam I*, ECF 49 at 2.

While this contempt petition was pending, McAdam filed an independent action on October 19, 2012, again alleging constitutional violations against the FDA and its Commissioner, Margaret Hamburg. *McAdam v. FDA*, CV 12-137-BLG-RFC-CSO (“*McAdam II*”). On

September 30, 2013, this Court entered Findings and Recommendations, recommending that McAdam's complaint be dismissed. *McAdam II*, *ECF 21*. The Court found that: (1) the United States had not waived its sovereign immunity for McAdam's claims; (2) "McAdam's attempt to obtain damages against Defendants is an impermissible collateral attack on the Consent Decree[,]" and (3) the complaint was barred by res judicata in that "[a]ll of the claims raised in the instant action could have been raised as defenses in [McAdam I]." *Id. at 14-16*. The District Court adopted the Findings and Recommendations in full and dismissed the action. *McAdam II*, *ECF 23*.

On April 3, 2014, McAdam commenced the instant action. *ECF 1*. His complaint alleges violations of his constitutional rights of equal protection (Count I) and free speech (Count IV), slander (Count IV (sic)<sup>3</sup>), that the FDA breached the Consent Decree (Count II), and that the FDA does not have jurisdiction under the Consent Decree to regulate black salves sold intrastate (Count III) or to regulate his sale

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<sup>3</sup>The complaint contains two counts identified as "Count IV." McAdam's slander claim is set forth in the second Count IV, hereinafter identified as "Count VI."

of “Lugol’s Iodine” (Count V). *Id.* He seeks compensatory damages for lost profits and emotional distress, injunctive relief, and punitive damages. *Id. at 11-12.*

### **III. PARTIES’ ARGUMENTS**

Defendants argue that: (1) Counts I and IV against the FDA and the individual Defendants sued in their official capacities are barred by sovereign immunity, *Defts’ Br. (ECF 8) at 15-19*; (2) McAdams’ second Count IV, alleging a claim for slander under the Federal Tort Claims Act fails for want of subject matter jurisdiction based on McAdam’s failure to exhaust administrative remedies, *id. at 19-21*; (3) Counts I through V constitute an improper collateral attack on the Consent Decree, which this Court has upheld several times, *id. at 21-23*; (4) Counts I through V are also barred by the doctrine of res judicata, *id. at 23-25*; and (5) McAdam’s complaint should be dismissed for insufficiency of service of process, *id. at 25-26*.

To date, McAdam has not filed a response to Defendants’ motion to dismiss, and the time for doing so has passed. *See* Local Rule 7.1(d)(1)(B)(I). The Court proceeds to the merits of the motion, but in doing so is not obligated “to scour the record” for a potential basis to deny Defendants’ motion to dismiss. *See, e.g., Carmen v. San Francisco*

*Unified Sch. Dist.*, 237 F.3d 1026, 1028–29 (9th Cir.2001); *Keenan v. Allen*, 91 F.3d 1275, 1279 (9th Cir.1996) (“[I]t is not our task, or that of the district court, to scour the record in search of a genuine issue of triable fact”).

#### IV. LEGAL STANDARDS

A cause of action may be dismissed under Rule 12(b)(1) “if the complaint, considered in its entirety, on its face fails to allege facts sufficient to establish subject matter jurisdiction.” *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 546 F.3d 981, 984-85 (9th Cir. 2008). When considering a motion to dismiss on jurisdictional grounds, the Court is to presume that the cause lies outside federal court limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Federal district courts lack subject matter jurisdiction over claims barred by sovereign immunity. *See F.D.I.C. v. Meyer*, 510 U.S. 471, 475 (1994) (“Sovereign immunity is jurisdictional in nature”); *United States v. Sherwood*, 312 U.S. 584, 586 (1941).

A cause of action may also be dismissed under Rule 12(b)(6) either when it asserts a legal theory that is not cognizable as a matter of law,

or if it fails to allege sufficient facts to support an otherwise cognizable legal claim. *SmileCare Dental Group v. Delta Dental Plan of California, Inc.*, 88 F.3d 780, 783 (9th Cir. 1996). In addressing a Rule 12(b)(6) challenge, the Court accepts all factual allegations in the complaint as true (*Hospital Bldg. Co. v. Trustees of the Rex Hospital*, 425 U.S. 738, 740 (1976)), and construes the pleading in the light most favorable to the nonmoving party. *Tanner v. Heise*, 879 F.2d 572, 576 (9th Cir. 1989). The Court is not, however, required to accept as true allegations that contradict exhibits attached to the Complaint or matters properly subject to judicial notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences. *Daniels-Hall v. Nat’l Educ. Ass’n*, 629 F.3d 992, 998 (9th Cir. 2010).

The Court’s standard of review under Rule 12(b)(6) is informed by Rule 8(a)(2) which requires that a pleading contain “a short and plain statement of the claim showing that the pleader is entitled to relief[.]” *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) (quoting Rule 8). To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft*, 129 S.Ct. at 1949. “A claim has



facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

As a general rule “a district court may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion.” *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001) (citation omitted). The Court may, however, consider “material which is properly submitted as part of the complaint[,]” or take judicial notice of “matters of public record” without converting a motion to dismiss to a motion for summary judgment. *Id.*, 250 F.3d at 688–89. Specifically, the Court may take judicial notice of other court proceedings. *Duckett v. Godinez*, 67 F.3d 734, 741 (9th Cir. 1995), and *Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1198 (9th Cir. 1988); *see also Burbank– Glendale– Pasadena Airport Authority v. City of Burbank*, 136 F.3d 1360, 1364 (9th Cir. 1998) (allowing judicial notice of pleadings in other cases).

## **V. DISCUSSION**

### **A. Constitutional Claims**

Counts I and IV, pled against the FDA and the individual Defendants in their official capacities, seek damages for alleged violations of McAdam’s constitutional rights. The Court concludes that

these claims are subject to dismissal based on sovereign immunity.

“It is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction.” *Jachetta v. United States*, 653 F.3d 898, 903 (9th Cir. 2011) (quoting *United States v. Mitchell*, 463 U.S. 206, 212 (1983)). Any waiver of sovereign immunity cannot be implied, but “must be unequivocally expressed in statutory text.” *Jachetta*, 653 F.3d at 903 (quoting *Lane v. Pena*, 518 U.S. 187, 192 (1996)). Absent a waiver, sovereign immunity shields the United States and its agencies from suit. *Meyer*, 510 U.S. at 475. The protection of sovereign immunity also extends to federal agents acting in their official capacities. *Hodge v. Dalton*, 107 F.3d 705, 707 (9th Cir. 1997).

The United States has not waived its sovereign immunity for actions seeking damages for constitutional violations. *See Holloman v. Watt*, 708 F.2d 1399, 1401-02 (9th Cir. 1983) (sovereign immunity not waived for claim under the Constitution for damages against the United States); *Arnsberg v. United States*, 757 F.2d 971, 980 (9th Cir.1984) (same). Accordingly, sovereign immunity applies, and the Court lacks subject matter over Counts I and IV insofar as they are pled against the FDA and the individual Defendants in their official

capacities. *See Consejo de Desarrollo Economico de Mexicali, A.C. v. United States*, 482 F.3d 1157, 1173 (9th Cir. 2007) (district court lacked subject matter jurisdiction over *Bivens* claim “because the United States has not consented to its officials being sued in their official capacities”). Accordingly, the Court will recommend in a subsequent opinion that Counts I and IV be dismissed.

**B. Claims Challenging the Consent Decree**

Counts II, III, and V are claims directly challenging or affecting the Consent Decree. Count II alleges that Defendants breached the terms of the Consent Decree by not advising McAdam whether the labels on his products complied with federal law. *ECF 1 at 6-7*. Count III alleges that McAdam should be allowed to sell “black salve in the state of his residence or place of manufacture[,]” contending that the FDA “has no authority on produces he sells and/or manufactures to entities and individuals whom reside in the state of Montana[.]” *Id. at 7-8*. Count V alleges that McAdam should be allowed to sell “Lugol’s Iodine” because he manufactures it consistent with a method used in 1824, prior to the creation of the FDA. *Id. at 9*. Defendants seek dismissal of these claims under Rule 12(b)(6), arguing that these claims are barred by res judicata. The Court agrees that these claims are

subject to dismissal on res judicata grounds.

“Under the doctrine of res judicata, ‘[a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action’ even if that judgment ‘may have been wrong or rested on a legal principle subsequently overruled in another case.’” *Paulo v. Holder*, 669 F.3d 911, 917 (9th Cir. 2011) (quoting *Federated Dep’t Stores, Inc. v. Moitie*, 452 U.S. 394, 398 (1981)).<sup>4</sup>

Res judicata encompasses the doctrines of issue preclusion and claim preclusion. Claim preclusion “bars litigation in a subsequent action of any claims that were raised or could have been raised in the prior action.” *Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 713 (9th Cir. 2001) (citation omitted). “It is immaterial whether the claims asserted subsequent to the judgment were actually pursued in the action that led to the judgment; rather, the relevant inquiry is whether they could have been brought.” *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg’l Planning Agency*, 322 F.3d 1064, 1078 (9th Cir.

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<sup>4</sup>Because the relevant underlying judgments are federal court decisions, the Court applies federal preclusion rules. *See Trevino v. Gates*, 99 F.3d 911, 923 (9th Cir.1996).

2003). Claim preclusion applies when there is: (1) an identity of claims; (2) a final judgment on the merits; and (3) identity or privity between parties. *Owens*, 244 F.3d at 713. “The central criterion in determining whether there is an identity of claims between the first and second adjudications is whether the two suits arise out of the same transactional nucleus of facts.” *Id.* at 714 (internal quotation marks omitted).

The prerequisites for res judicata are satisfied. Counts II, III, and V directly affect the enforceability of the Consent Decree, which was at issue in both *McAdam I* and *McAdam II*. McAdam could have raised these claims as defenses in *McAdam I*, as this Court specifically found in *McAdam II*. *See F&R, McAdam II, ECF 21 at 15-16* (“All of the claims raised in the instant action could have been raised as defenses in the Enforcement Case”). This Court has on separate occasions both upheld and enforced the Consent Decree against McAdam in *McAdam I*, and rejected McAdam’s subsequent challenges against it in *McAdam II*. Counts II, III, and V are subject to dismissal on res judicata grounds, and the Court will recommend in a subsequent opinion that such claims be dismissed pursuant to Rule 12(b)(6).

### C. Slander Claim

Defendants acknowledge that McAdam's slander claim under the FTCA (Count VI) falls within a well established exception to sovereign immunity, but argue that this claim should nonetheless be dismissed because McAdam has failed to exhaust administrative remedies under 28 U.S.C. § 2675(a). *ECF 8 at 19-20*. To support their argument, Defendants submit the Declaration of Daretia Hawkins, a senior attorney in the Office of the General Counsel responsible for evaluating administrative tort claims filed under the FTCA. *See ECF 7-1*. Hawkins represents that after conducting an official search, she has determined that McAdam has not filed an administrative tort claim with her office in relation to this case. *Id. at ¶¶ 4-6*.

Rule 12(d) states that “[i]f, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56.” Hawkins' declaration is material outside the pleadings that the Court has considered and not excluded. This declaration contains facts that bear directly on Defendants' motion and claim for relief. Accordingly, the Court must convert the motion to dismiss, insofar as it seeks dismissal of McAdam's slander claim under the

FTCA, into a motion for summary judgment. *See San Pedro Hotel Co., Inc.*, 159 F.3d 470, 477 (9th Cir. 1998) (citing with approval *Grove v. Mead School Dist. No. 354*, 753 F.2d 1528, 1532 (9th Cir. 1985) (holding that a “represented party who submits matters outside the pleadings to the judge and invites consideration of them has notice that the judge may use them to decide a motion originally noted as a motion to dismiss, requiring its transformation to a motion for summary judgment”)).

Pursuant to Rule 12(d), the Court will afford McAdam 21 days from the date of this opinion to file a response to Defendants’ motion for summary judgment on his slander claim (Count VI). McAdam is advised that if he fails to file a timely response, the Court will recommend dismissal of his slander claim.

#### **D. Service of Process**

Rule 4(i) provides specific procedures that must be followed to effect service upon the United States and its agencies, corporations, officers, or employees. If a party fails to effect service in compliance with Rule 4(I), the Court lacks personal jurisdiction over the United States and the case must be dismissed. *See Reynolds v. United States*, 782 F.2d 837, 838 (9th Cir. 1986); *Ruiz v. Geithner*, 2009 WL 3232160

\*5 (S.C. Cal. 2009).

To serve the United States with process, a party must send the summons and complaint by registered or certified mail to the Attorney General of the United States in Washington, D.C., and either personally deliver them to the United States Attorney (or his or her designee) for the district where the case is brought or send them to the civil process clerk for that district's U.S. Attorney's Office by registered or certified mail. Rule 4(i)(1).

To serve an agency of the United States or an officer or employee sued in an official capacity, a party must satisfy the Rule 4(i)(1) requirements for serving the United States and further send the summons and complaint to the agency, officer, or employee by registered or certified mail. Rule 4(i)(2).

Finally, to serve an officer or employee sued in an individual capacity, a party must serve the United States and also serve the officer or employee in accordance with the individual service rules. Rule 4(i)(3); *see also* Rule 4(c)(2) ("Any person who is at least 18 years old and not a party may serve a summons and complaint").

McAdam is required to promptly file proof of service of process. *Local Rule 4.3(a)*. Yet he has failed to prove proper service on any



Defendant as required by Rule 4(i). Specifically, McAdam has not served copies of the summons and complaint by certified or registered mail on the Attorney General, the FDA, or any of the officers or employees sued in their official capacities. McAdam has also failed to individually serve the officers and employees sued in their individual capacities.

McAdam did, however, serve the United States Attorney.

Therefore, the Court will allow McAdam a reasonable time to cure the defective service. The Court will afford McAdam 28 days to properly effectuate service, consistent with Rule 4(i), upon all Defendants.

Failure to timely and adequately serve these Defendants will subject all of McAdam's claims to dismissal.

## **VI. CONCLUSION**

Based on the foregoing, IT IS ORDERED that:

1. Defendants Motion to Dismiss is converted to a motion for summary judgment insofar as it seeks dismissal of Count VI, alleging a claim for slander under the FTCA. McAdam must respond to this motion for summary judgment on Count VI on or before **July 21, 2014**, or the Court will recommend dismissal of Count VI; and
2. On or before **July 28, 2014**, McAdam must effectuate proper

service on the FDA and the individual Defendants in both their official and individual capacities. Failure to do so may result in dismissal of McAdam's complaint.

DATED this 30th day of June, 2014.

/s/ Carolyn S. Ostby  
United States Magistrate Judge